UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/481,733	01/11/00	WARREN	P DIVER1240-5

EXAMINER	
SLOBODYANSKY,E	
ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 01/30/01

HM12/0130

LISA A HAILE PHD
GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE1600
SAN DIEGO CA 92121-2189

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/481,733	Applicant(s) Warren et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Jan 8, 2001*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-14 and 16-24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14 and 16-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2,5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed January 8, 2001 (Paper No. 8) canceling claim 15 has been entered.

Claims 1-24 are pending.

Election/Restriction

Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 and 16-24 are examined.

Specification

The specification is objected to because it refers to the biological deposits at ATCC without indicating ATCC Deposit No. For example, on pages 2 and 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites DNA sequences comprising at least 15 nucleotides encoding an aminotransferase of SEQ ID NOS :25-32. Therefore, claim 1 is directed to a genus of DNA molecules encoding any aminotransferase from any source. There structural limitations amounts to about 1% identity to a DNA encoding any of SEQ OD NOs:25-32. The specification teaches the structure of only a single representative species of such DNAs. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding an aminotransferase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-14 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding an enzyme of SEQ ID NOs: 25-32, does not reasonably provide enablement for any

polynucleotide or probe having at least 70% identity to a polynucleotide comprising 15 or 10-50 bases of a polynucleotide encoding an enzyme of SEQ ID NOs: 25-32. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-14 and 17-24 are so broad as to encompass any polynucleotide having at least 70% identity to a polynucleotide comprising 15 (10-50) bases of a polynucleotide encoding an enzyme of SEQ ID NOs: 25-32. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the

desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any nucleic acid encoding an enzyme with at least 70% identity to the enzymes of SEQ ID NOs: 25-32 because the specification does **not** establish: (A) regions of the structure which may be modified without effecting encoded aminotransferase activity and/or its utility as a nucleic acid probe; (B) the general tolerance of aminotransferases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including an enormous number of nucleic acids encoding amino acid modifications of the aminotransferases of SEQ ID NOs: 25-32. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

determination of aminotransferase genes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 16 and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that claim 1(d) is intended to be drawn to a fragments of at least 15 bases. However, this is unclear because the whole claim is drawn to a DNA encoding an enzyme.

Claim 16 is confusing as reciting "a protein encoding a polypeptide". The examiner made a note of it in the Office action mailed December 7, 2000, last paragraph on page 3.

Claims 17-24 are indefinite in the recitation of "probe" as it is unclear if this term imparts any limitations (either structural or functional) on the nucleic acids claimed. Does the term "probe" require that the nucleic acid be labeled? or must hybridize to a

particular nucleic acid? If it must hybridize to a particular nucleic acid must the hybridization be specific?

Claims 17-24 are indefinite in the recitation of "moderate to highly stringent conditions" as the specification does not define what conditions constitute "moderate to highly stringent". While page 8, last paragraph through page 9, 2nd paragraph, of the specification describes non-limiting examples of some conditions which are intended to be "stringent", there is nothing to suggest that these conditions are "moderate to highly stringent nor whether other conditions would not also be included within the scope of this term and in the art what is considered "moderate to highly stringent" varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NOs:25-32, a sequence must be to be included within the scope of these claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,814,473. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: nucleic acids encoding SEQ ID NOs:25-32 or fragments thereof of at least 15 bases.

Claims 1-14 and 17-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,013,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: nucleic acids encoding SEQ ID NOs:25-32, fragments thereof of at least 15 bases and a probe of 15-50 nucleotides of SEQ ID NOS: 17-24.

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/412,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a polynucleotide having at least 70% identity to a nucleic acid encoding SEQ ID NOs:25-32.

no TD filed

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

January 26, 2001